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MERCK
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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville, MD 20852

RE: [Docket No. 99D-0296] FDA/HHS: Draft Guidance for Industry on Formal Meetings with Sponsors and Applicants for PDUFA Products; Availability
And
RE: [Docket No. 99D-0297] FDA/HHS: Draft Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

Merck & Co., Inc, is a leading worldwide, human health product company. Through a combination of the best science and state-of-the-art medicine, Merck's R & D pipeline has produced many of the most important pharmaceutical products on the market, today.

In the course of bringing our product candidates through developmental testing and clinical trials, Merck scientists regularly meet with FDA staff to address scientific and procedural issues, so we are directly affected by the *Draft Guidance for Industry on Formal Meetings with Sponsors and Applicants for PDUFA Products*. Although most of our interactions with FDA staff are collegial, there have been scientific or administrative issues about which we have disagreed. Some have required our pursuit of adjudication of differences via different administrative routes. Since we expect that scientific debate will often lead to differences of opinion requiring resolution, we expect that the *Draft Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level* will be one which may affect us in the future, as well. For these reasons, we are very interested in these two Draft Guidances which we have reviewed in tandem.

After careful consideration of both Draft Guidances together, we conclude that publication of these draft guidances does not change the process which a sponsor will follow prior to a formal meeting of any kind. Therefore, since the process will not be altered, the paperwork burden for industry remains essentially the same.

For the record, however, FDA estimates of time spent in preparation of materials to comply with both guidances may be a relatively accurate accounting of time used in *administrative* preparation of information for *routine* meetings or for dispute resolution of a *procedural* nature. Administrative activities prior to a meeting include: collating, copying, packaging and transmitting the required statement(s) of purpose (for the meeting), an agenda, a background information package and appropriate forms.

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In addition, it should be noted for the record that FDA underestimates the time required to prepare for meetings where more than one issue will be addressed or for meetings to resolve disputes of a *scientific* or *technical* nature. In those cases, more creative technical materials must be revised (or re-created), reviewed and edited, and slide materials will also be prepared to accompany presentations at the meetings. Therefore, when more than one scientific issue will be discussed at a single FDA meeting, which is most often the case, the estimated burden of 10 hours for preparation of background materials may be multiplied by the number of technical disciplines involved, in order to more accurately reflect the burden on the sponsor.

In summary, these two draft guidances do not add to the paperwork burden that already exists. However, the paperwork estimates noted in each guidance may be considered accurate for *administrative* tasks, only. FDA estimates understate the time required for creative writing and editing tasks associated with preparation of paperwork prior to a formal meeting with FDA staff, when many issues will be discussed or when complicated technical topics will be debated.

We appreciate your consideration of our comments.

Sincerely,

Marie A Gray for David W Blois

David W. Blois, PhD

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